DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 29, 2015

DSM Biomedical
Mr. Tom Maguire
Senior Director Global Clinical and Regulatory
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K143716
Trade/Device Name: DSM Biomedical DPR Cable
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: September 16, 2015
Received: September 17, 2015

Dear Mr. Maguire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

The DPR Cable is intended for:

- Spinal applications include sublaminar and intraspinous process wiring for trauma applications.
- Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty.
- Sternotomy indications including the “rewiring” of osteomized sternums.
- Trauma surgery indications including olecranon, ankle, patella and some shoulder fracture rewiring.

The device is intended for single patient use only.

Prescription Use____X_____AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

DSM
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510(k) Summary

K143716

Submitted By: DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Tom Maguire
Sr. Director, Global Clinical & Regulatory Affairs
E: Tom.Maguire@dsm.com
P: 484-713-2146
F: 484-713-2903

Date Prepared: October 26, 2015

Device:

Trade Name:	DPR Cable
Common/Usual Name:	Orthopedic Wire
Classification Name:	Bone Fixation Cerclage
Classification Regulation:	21 CFR 888.3010
Device Class:	Class II
Device Code:	JDQ
Advisory Panel:	General and Plastic Surgery

Predicate: Titanium Alloy Songer Cable System/ Atlas Cable System (Medtronic Sofamor Danek , K920201)

Reference Devices: Iso-Elastic Cable (Kinamed Inc., K102834)
Orthopedic Polyethylene Cable (Smith&Nephew, K924141)

Device Description:

The DPR Cable is a flexible, multi-strand ultra-high molecular weight polyethylene

(UHMWPE) cerclage cable. The device is intended to provide stabilization of bony segments.

The DPR Cable is made of woven ultra-high molecular weight polyethylene fibers which incorporate bismuth trioxide (Bi_2O_3). The addition of bismuth trioxide allows for radiographic visualization both during and after surgical procedures. The device is supplied sterile in double-layer packages. The DPR Cable is intended for single patient use only. DPR Cable is MR safe.

Intended Use:

The DPR Cable is intended:

- Spinal applications including sublaminar and intraspinous process wiring for trauma applications.
- Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty.
- Sternotomy indications including the "rewiring" of osteomized sternums.
- Trauma surgery indications including olecranon, ankle, patella and some shoulder fracture rewiring.

The device is intended for single patient use only.

Technological Characteristics:

Characteristic	DSM Biomedical DPR Cable K143716	Medtronic Sofamor Danek Titanium Alloy Songer Cable System/Atlas™ Cable System K920201
Indications for Use	The DPR Cable is intended: • Spinal applications including sublaminar and intraspinous process wiring for trauma applications. • Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty. • Sternotomy indications including the "rewiring" of osteomized sternums. • Trauma surgery indications including the olecranon, ankle, patella and some shoulder fracture rewiring. The device is intended for single patient use only.	The Atlas™ Cable System can be utilized anywhere monofilament wires have been previously found to be indicated. The indications are: • Spinal applications would include sublaminar and intraspinous process wiring for trauma applications. Another application would be the use of Atlas™ Cable System for instrumentation involved in the correction of scoliotic,kyphotic and lordotic deformities. The stainless steel system may also be used with other stainless steel spinal implants such as the Unit Rod or Luque Rod or wherever "wiring" may help secure the attachment of other implants. The titanium system may also be used with other titanium implants. • Trochanteric reattachment after trochanteric osteotomy following

Characteristic	DSM Biomedical DPR Cable K143716	Medtronic Sofamor Danek Titanium Alloy Songer Cable System/Atlas™ Cable System K920201
		total hip arthroplasty. • Sternotomy indications would include the "re-wiring" of osteomizing sternums. • Trauma surgery indications would include olecranon, ankle, patella and some shoulder rewiring.
Materials of Composition	Dyneema Purity® UHMWPE and Bi_2O_3	Titanium Steel and Titanium Alloy
Device Characteristics	Flexible, high strength	High strength
Radiopaque	Yes	Yes
Fixation	Knot	Integral Crimp
Dimensions	4 mm	1 mm diameter
Tensile Strength of fixated loop	2289+/-35	1005+/-49
Fatigue Strength	1559N	<44.5N
Biocompatible	Yes	Yes
Reusable	Single Use Only	Single Use Only
Sterilization Method	EtO	Irradiation
Packaging	Double layer	Not available

Biocompatibility and Performance Data:

Biocompatibility testing

The biocompatibility of the materials used in the manufacturer of the DPR Cable, Dyneema Purity® fibers and bismuth trioxide, are established by their long historical clinical use in medical devices and the combination of these materials does not raise any new questions of safety and effectiveness. Cytotoxicity and leaching was performed on the Dyneema Purity® RP material.

Biomechanical testing included fatigue strength, tensile force, creep and wear-debris and knot strength. Testing results indicate that the device is equivalent to the predicate device.

Substantial Equivalence:

The DPR Cable is substantially equivalent in intended use, tensile strength, and fixation strength to the predicate device (Titanium Alloy Songer Cable System/Atlas™ Cable System, Medtronic Sofamor Danek, K920201). The DPR Cable is substantially equivalent to the material characteristics and creep and wear performance of the reference devices (Iso-Elastic Cable, Kinamed Inc., K102834 and Orthopedic Polyethylene Cable, Smith & Nephew, K924141).